

# PATENT ABSTRACTS OF JAPAN

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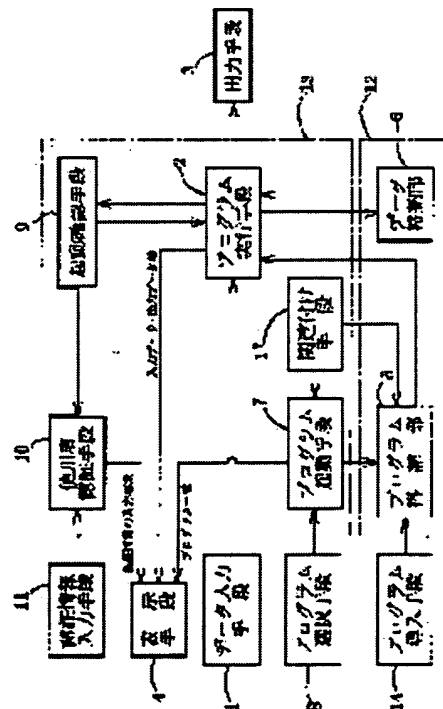
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## (54) PROGRAM SELECTION AND START-UP SYSTEM

(57)Abstract:

PROBLEM TO BE SOLVED: To provide a low cost program selection and start-up system by which checking of the operation during system operation is easily performed.

SOLUTION: A GLP, etc., is guaranteed by surely performing the checking of operation for only part of a program after start of the system operation and the cost is reduced since no unnecessary program is required to be introduced by providing a program storage part 5 to store a plurality of programs the functions of which are divided by every data item and/or operation, a program start-up means 7 in which the plurality of programs are registered and which starts either of selected programs among the registered programs, a display means 4 to display a list of programs registered in the program start-up means 7 and a program selecting means 8 to select the program which is desired to be started from the displayed list of programs.



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**CLAIMS**

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**[Claim(s)]**

[Claim 1] The program storing section which stores two or more programs by which functional partition was carried out for every data item and/or actuation, A starting means chosen among the programs by which registration of two or more above-mentioned programs was registered and carried out [ above-mentioned ] to start one of programs at least, Program selection starter system carried out [ having a program selection means to choose the program which desires starting from the list of the programs displayed on a display means to display the list of the programs registered into the above-mentioned starting means, and the above-mentioned display means, and ] as the description.

[Claim 2] It is the program selection starter system used for the chemical trial data control which manages data, such as symptom change of the living body at the time of medicating a living body with a chemical. The program storing section which stores two or more programs by which functional partition was carried out for every data item and/or actuation, A starting means chosen among the programs by which registration of two or more above-mentioned programs was registered and carried out [ above-mentioned ] to start one of programs at least, Program selection starter system carried out [ having a program selection means to choose the program which desires starting from the list of the programs displayed on a display means to display the list of the programs registered into the above-mentioned starting means, and the above-mentioned display means and ] as the description.

[Claim 3] Program selection starter system [ equipped with a seizing acknowledgment means to check whether either is continue starting among the programs by which starting was carried out / above-mentioned / for every predetermined time, and a user authentication means to ask for the input of a user's authentication information for every predetermined period while starting of one of programs is continuing being checked by the above-mentioned seizing acknowledgment means ] according to claim 1 or 2.

[Claim 4] Program selection starter system given in any 1 term of claims 1-3 which are what is used for the toxicity test of the chemical using the animal as a living body.

[Claim 5] Program selection starter system according to claim 3 or 4 which is equipped with an authentication information maintenance means to hold the effectiveness information on the user authentication by the user authentication means, starts program execution based on the effectiveness information held for the above-mentioned authentication information maintenance means on the occasion of starting of each program when authentication is effective, and starts program execution when authentication is invalid.

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**DETAILED DESCRIPTION**

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[Detailed Description of the Invention]

[0001]

[Field of the Invention] weight, the amount of baiting, the amount of water intakes, biochemical inspection, and clinical manifestation observation of the living body at the time of this invention mainly medicating a living body with a chemical -- it is related with the program selection starter system which can apply -- pathological findings, urine volume, ophthalmology-inspection, hemology-inspection, etc. to the chemical trial data control which records, manages and totals.

[0002]

[Description of the Prior Art] In addition to this, checking them by the nonclinical test which uses animals, such as a rat and a mouse, before drugs, agricultural chemicals and a food additive, and safeties to the body, such as carcinogenic, toxicity, etc. of a chemical, go into a clinical trial although a clinical trial is performed in advance of marketing is performed.

[0003] Safety tests, such as a chemical which used such an animal The single-dose toxicity study to which toxicity will occur if a medicine is prescribed for the patient how much per time, and the toxic description clarifies something, The repeated-dose toxicity study which clarifies the dosage and the toxic description that the dosage and a toxic change to which toxicity sees and is stopped at the time of repeated-dose administration see, and are not stopped, The reproduction test which clarifies effect affect reproduction of a parent animal, effect about next-generation generating, etc., The mutagenicity test which clarifies existence of the property which induces the matter which shows trauma nature to DNA, and mutation is begun, and various kinds of trials, such as a carcinogenicity test, a skin sensitization test, skin photosensitization study, and dependence study, are performed.

[0004] Each above-mentioned trial actually medicates an animal with a chemical, and is performed by totaling and analyzing the data which extracted by performing measurement of an amount, observation, a pathology organization view of a clinical manifestation, etc. of weight, food, water, urine, etc.

[0005] Since such a safety test is performed in advance of the clinical trial which actually medicates the body with the chemical and performs it and the body is finally affected, it is necessary to understand correctly the effect a chemical affects a living body, and to analyze it. For this reason, the computer system has been used for record, and management and analysis of data from the former.

[0006] As mentioned above, since chemicals including drugs are what affects the body, severe criteria are prepared in the data control of the above safety tests in each government office including the Ministry of Health and Welfare so that an alteration may not be added to data. Such a standard is named generically, and is called "GLP (Good Laboratory Practice)", and the computer system which manages data with a natural thing also needs to fulfill the standard of GLP.

[0007] And although it cannot be overemphasized that the design of a system itself needs to conform to GLP, since know-how with a commercial scene very peculiar at a niche is required, as for the above-mentioned system, application of the system concerned serves as a large sum very much. Moreover, when a system is introduced, it needs of operation to be checked at the time of the installation which checks whether GLP is suited and it operates certainly. Moreover, also after operation of a system is started, when some systems have version up, it must check suiting GLP and operating certainly again about the whole system, must leave as a document, and must guarantee that there is no alteration in the system itself.

[0008]

[Problem(s) to be Solved by the Invention]

[0009] However, in the conventional system, all functions serve as a package, installation and employment of are done, and GLP etc. is guaranteed with the whole package. For this reason, even when the function of some systems had version up etc., the whole system had to perform the check of operation again. In order that the staff of 2 - trinominal may usually take the time amount for three months or more to such a check of operation, the actual condition is that the check of operation by the bug correction or functional rise after systems operation initiation was not performed at all substantially. And in the system by which all functions were package-ized, many functions in which it is hardly used are added like before, and it had become the factor which pulls up system-wide cost.

[0010] Moreover, in the conventional system, in order to work as it is until it terminates a system, even if an input person etc. has modification on the way after that although a user is attested at the time of starting of a system, decision of an input person was not completed substantially, but when guaranteeing GLP etc., there was a problem.

[0011] This invention was made in view of such a situation, and the check of operation in systems operation is easy, and aims it at the system distribution which is program selection starter system [ low cost moreover ], and can unify authentication.

[0012] [Means for Solving the Problem] In order to attain the above-mentioned purpose, the program selection starter system of this invention The program storing section which stores two or more programs by which functional partition was carried out for every data item and/or actuation, A starting means chosen among the programs by which registration of two or more above-mentioned programs was registered and carried out [ above-mentioned ] to start one of programs at least, It carries out having a program selection means to choose the program which desires starting from the list of the programs displayed on a display means to display the list of the programs registered into the above-mentioned starting means, and the above-mentioned display means as the 1st summary.

[0013] Moreover, the program selection starter system of this invention It is the program selection starter system used for the chemical trial data control which manages data, such as symptom change of the living body at the time of medicating a living body with a chemical. The program storing section which stores two or more programs by which functional partition was carried out for every data item and/or actuation, A starting means chosen among the programs by which registration of two or more above-mentioned programs was registered and carried out [ above-mentioned ] to start one of programs at least, It carries out having a program selection means to choose the program which desires starting from the list of the programs displayed on a display means to display the list of the programs registered into the above-mentioned starting means, and the above-mentioned display means as the 2nd summary.

[0014] Namely, the program selection starter system of this invention The program storing section which stores two or more programs by which functional partition was carried out for every data item and/or actuation, A starting means chosen among the programs by which registration of two or more above-mentioned programs was registered and carried out [ above-mentioned ] to start one of programs at least, It has a program selection means to choose the program which desires starting from the list of the programs displayed on a display means to display the list of the programs registered into the above-mentioned starting means, and the above-mentioned display means. Thus, since two or more programs by which functional partition was carried out for every data item and/or actuation exist independently, when a part of programs have version up etc., if the check of only the program of operation is performed, it will come to end. Therefore, the check of operation after systems operation initiation can be ensured, and GLP etc. can be guaranteed now. Moreover, since the low unnecessary program of possibility of using it ends even if it does not introduce it, it can also reduce the introductory cost and employment cost of a system sharply.

[0015] A seizing acknowledgment means to check whether either is continue starting in the program selection starter system of this invention among the programs by which starting was carried out [ above-mentioned ] for every predetermined time, When it has a user authentication means to ask for the input of a user's authentication information for every predetermined period while starting of one of programs is continuing being checked by the above-mentioned seizing acknowledgment means Since a user is attested for every predetermined period while either of the started programs is continuing starting, an input person etc. can be decided substantially and GLP etc. can be guaranteed certainly.

[0016] In the program selection starter system of this invention, since a variety of [ the toxicity test of the

chemical which used the animal as a living body / that it is huge and ] data exist and the class of required data changes with users in many cases in being what is used for the toxicity test of the chemical using the animal as a living body, only the required high program of possibility of using it can be introduced, and system-wide cost can be reduced sharply. Moreover, since two or more observers can perform a data input etc. by turns, the effectiveness of this invention which an input person etc. can check for every fixed period is remarkable, and effective.

[0017] When the registered program is started in the program selection starter system of this invention, the above-mentioned program checks starting of a user authentication means. When the user authentication means is not started, in starting a user authentication means Since it becomes unnecessary to attest a user while one of programs is started, since authentication of two or more programs with one user authentication means is manageable whenever it starts other programs, working efficiency improves. Moreover, since a user authentication means is not started in program executions other than the registered program, memory space is not consumed beyond the need, therefore the evil of execution speed falling does not arise.

[0018] In the program selection starter system of this invention, it has an authentication information maintenance means to hold the effectiveness information on the user authentication by the user authentication means. It is based on the effectiveness information held for the above-mentioned authentication information maintenance means on the occasion of starting of each program. In order not to perform user authentication for every program starting if user authentication is effective in starting program execution when authentication is effective, and starting program execution, when authentication is invalid, the overlapping time and effort can be saved and it is user-friendly.

[0019]

[Embodiment of the Invention] Below, the gestalt of operation of this invention is explained in detail.

[0020] Drawing 1 is the system configuration Fig. showing the gestalt of 1 operation of the program selection starter system of this invention. This system is what shows the example which applied this invention to the chemical trial data management system. A data input means 1 to input data, such as an amount of the weight when actually medicating an animal with a chemical, food, water, urine, etc., biochemical inspection, hemology-inspection, observation of a clinical manifestation, and various kinds of pathological findings, The data inputted into this data input means 1 were received, and it has a program execution means 2 to perform each program which mentions later and to perform the total of data etc.

[0021] Moreover, an output means (for example, printer) 3 to output to a document etc. the data to which the total etc. was carried out with the above-mentioned program execution means 2, and a display means (for example, display) 4 to display various kinds of information at the time of a data input and data output etc. are formed in the above-mentioned system. Furthermore, it has the data storage section 6 which stores the inputted data via the program execution means 2. In drawing, 12 is storage, such as a hard disk and MO, and 13 is the computer apparatus equipped with a central processing unit, memory, etc.

[0022] Here, processing of the usual data input, a total, etc. is performed by each means which mentioned the above-mentioned system above. That is, the data inputted with the data input means 1 are stored in the data storage section 6 through the program execution means 2, and required information besides the inputted data is displayed by the display means 4 during an input. Moreover, when the total of input data etc. is performed, the totaled data are outputted from the output means 3, and required information besides the data outputted is displayed on the display means 4.

[0023] And the above-mentioned system is equipped with the program storing section 5 which stores two or more programs. Two or more programs by which functional partition was carried out for every data item and/or actuation, such as an output of the total and pathological findings of the input and pathological findings of the output and pathological findings of the total data of the total and weight of the input and weight of weight, are stored in the above-mentioned program storing section 5. The program stored in the above-mentioned program storing section 5 can be introduced now at any time with the program installation means (for example, CD-ROM drive etc.) 14.

[0024] Moreover, each program stored in the above-mentioned program storing section 5 was registered into the above-mentioned system, and equips it with a program starting means 7 to start the program chosen by the user among the programs by which registration was carried out [ above-mentioned ]. Moreover, the correlation means 17 which associates the storing location of each program in the program storing section 5 and the registration location of the program to the program starting means 7 is established.

[0025] Furthermore, the list of the programs registered into the above-mentioned program starting means 7 has a program selection means 8 to choose the program whose user desires starting from the list of the programs which were displayed on the display means 4 and displayed on the above-mentioned display means 4.

[0026] Using input means, such as a mouse, the program of the request which wishes to start is chosen from the program lists displayed on the menu 14 displayed on Screen 16 of the display means 4, and selection of the program by the above-mentioned program selection means 8 is performed by doubling and clicking the pointer (not shown) of a mouse to the icon 15, as shown in drawing 2 . In addition, a program may be started only one and may start two or more.

[0027] And the program chosen with the program selection means 8 is started by the program starting means 7 based on the correlation information by the correlation means 17. Starting of a program reads a program from the program storing section 5 in memory, develops, and is performed by acquiring activation authority from operation system. And the program started by the program execution means 2 is performed.

[0028] Furthermore, a seizing acknowledgment means 9 to check whether it is started with the program starting means 7, and the program currently performed with the program execution means 2 is continue being started to every predetermined time (for example, 5 minutes) is formed in the above-mentioned system. This seizing acknowledgment actuation is performed by asking operation system whether the program is developed and performed on memory.

[0029] Moreover, while starting of one of programs is continuing being checked by the above-mentioned seizing acknowledgment means 9, a user authentication means 10 to ask every predetermined period (for example, 30 minutes) for the input of a user's authentication information is established. Furthermore, according to the demand of the authentication information input of the above-mentioned user authentication means 10, an authentication information input means 11 to input authentication information is established. Here, the period (authentication time amount) which requires the input of authentication information is set up for a long time than the time amount (seizing acknowledgment time amount) which checks starting of a program.

[0030] The demand of the above-mentioned authentication information input is performed by displaying the password input screen which urges the input of a password to the display means 4. Moreover, the input of authentication information is performed by entering a password into the above-mentioned password input screen using a keyboard.

[0031] Furthermore, the above-mentioned seizing acknowledgment means 9 is started by the above-mentioned program, if the above-mentioned program checks starting of an authentication program (user authentication means 10) and the seizing acknowledgment means 9 is not started, when the program registered into the program starting means is started. Since it becomes unnecessary to attest users, such as a password input, while one of programs is started, since authentication of two or more programs with one user authentication means 10 is manageable by doing in this way whenever it starts other programs, working efficiency improves. Moreover, since the seizing acknowledgment means 9 is not started in program executions other than the registered program, memory space is not consumed beyond the need and the evil of execution speed falling does not arise.

[0032] Below, actuation of the above-mentioned chemical trial data management system is explained based on the flow chart shown in drawing 3 . In addition, in drawing, "S" means a step.

[0033] First, the list of the programs registered is displayed on the display means 4 by starting a launcher program (program starting means 7) (S10: refer to drawing 2 ). Subsequently, out of the menu 14 displayed on Screen 16 of the display means 4, it clicks on the icon 15 of the program for which it asks, a desired program is chosen (S20), and a program is started (S30). At this time, if starting of an authentication program (seizing acknowledgment means 9) is checked and the seizing acknowledgment means 9 is not started by the program by which starting was carried out [ above-mentioned ], the seizing acknowledgment means 9 is started by the above-mentioned program (S70).

[0034] And if it is necessary to start the program of further others and return (S40) and its need will not be in step 1, the started program will be performed and processing according to each program, such as data inputs of weight, food, water, urine, etc., such as an amount and an observation view of a pathology symptom, and a total of input data, a document output of total data, will be performed (S50). And if there is the need for an activity succeeding and return and its need will not be in step 10, it will end (S60).

[0035] On the other hand, it checks whether when waiting (S80) and the above-mentioned seizing

acknowledgment time amount always pass, the program has started the progress of seizing acknowledgment time amount (for example, 5 minutes) which checks whether the program which continued starting an authentication program in parallel to the above-mentioned processing, and was started with the program starting means 7 has started (S90).

[0036] Subsequently, if one of programs has started (S100), it will wait for progress of the authentication time amount (for example, 30 minutes) which attests a user (S110). If the above-mentioned authentication time amount has not passed, return and the actuation which waited for and mentioned above the seizing acknowledgment passage of time again are repeated to step 80.

[0037] In step 110, progress of authentication time amount requires the input of authentication information of a user by directing a halt of activation to two or more programs performed now, and displaying a password input screen on the display means 4 at the time, etc. (S120). And if authentication information, such as an exact password, is inputted, while directing the restart of activation to the program which is in a halt condition, return and the actuation mentioned above are again repeated to step 8 (S130).

[0038] If authentication information is not inputted, it returns to step 120 and the input of authentication information is required again -- on the other hand in step 130, the entered password is mistaken. And even if it repeats the number of regularity times, when an exact password is not entered and a user's authentication is not completed, to the program which is in a halt condition, forced termination of activation is directed and a program is ended in response to termination directions.

[0039] On the other hand, if all the programs started with the program starting means 7 are completed in step 100, it will end. Thus, since a user is attested for every predetermined period while either of the started programs is continuing starting, an input person can decide substantially and GLP etc. can be guaranteed certainly.

[0040] Thus, since two or more programs by which functional partition was carried out for every data item and/or actuation exist independently according to the above-mentioned system, when a part of programs have version up etc., if the check of only the program of operation is performed, it will come to end. Therefore, the check of operation after systems operation initiation can be ensured, and GLP etc. can be guaranteed now. Moreover, since the low unnecessary program of possibility of using it ends even if it does not introduce it, it can also reduce system-wide cost sharply.

[0041] The above-mentioned system is used suitable for the toxicity test of the chemical which used the animal as a living body. It is because a variety of [ the above-mentioned toxicity test / that it is huge and ] data exist, the class of required data changes with users in many cases, so only the required high program of possibility of using it can be introduced and system-wide cost can be reduced sharply. Moreover, it is because two or more observers perform a data input etc. by turns in many cases, so the effectiveness of this invention which an input person etc. can check for every fixed period is remarkable and effective.

[0042] Drawing 4 is the system configuration Fig. showing the gestalt of operation of the 2nd of this invention.

[0043] The user program by which this system is performed with a program execution means starts an authentication program (user authentication means 10). Moreover, it judges whether it has an authentication information maintenance means 18 to hold the authentication information concerning effective/invalid of authentication by the user authentication means 10, a user program communicates with an authentication program, and the above-mentioned system continues activation of the user program itself. Furthermore, itself judges termination so that itself may not start an authentication program repeatedly. The same sign is given to the part that it is the same as that of the gestalt of implementation of the above 1st, and same except it.

[0044] Drawing 5 is a flow chart which shows actuation of the above-mentioned system. In addition, in drawing, "S" means a step.

[0045] That is, the list of the programs registered is first displayed on the display means 4 by starting a launcher program (program starting means 7) (S10: refer to drawing 2 ). Subsequently, if it clicks on the icon 15 of the program for which it asks and a desired user program is chosen out of the menu 14 displayed on Screen 16 of the display means 4 (S20), starting of a user program will be started (S30). And to step 10, when not ending a launcher program, return and when that is not right, it ends (S40).

[0046] If starting of a user program is started in step 30, starting of an authentication program (seizing acknowledgment means 9) will be started (S50). If an authentication program is started, if it has already performed, in order to prevent double starting, it will progress to step 90, and the check of whether the authentication program has already been performed is performed, and if starting actuation of an authentication

program is not performed, it will progress [ it ends, and ] to step 100.

[0047] Step 100 requires the input of authentication information, such as a password and user ID, from the authentication information input means 11. At step 110, the password and user ID which were inputted in step 100 judge whether it is it is just and effective or invalid. In step 110, if authentication is effective, the authentication owner effect will be notified to a user program, and the information on the authentication owner effect will be held for the authentication information maintenance means 18 (S115). On the other hand, if authentication is invalid in step 110, an authentication invalid will be notified to a user program and the information on an authentication invalid will be held for the authentication information maintenance means 18 (S120).

[0048] Subsequently, if the above-mentioned authentication time amount has not passed progress of the authentication time amount (for example, 30 minutes) which attests a user in waiting (S130) and step 140, return and the actuation which waited for and mentioned the authentication passage of time above again are repeated to step 130. If authentication time amount has passed in step 140, it will check whether the user program is performed (S150). And if the user program is performed at least one in step 160, return and the actuation which waited for and mentioned the authentication passage of time above again will be repeated to step 130. An authentication program is ended if one is not performed for the user program in step 160.

[0049] On the other hand, after starting of a user program is started in step 30 and starting of an authentication program is started in step 50, it progresses to step 60 and information concerning effective/invalid of the authentication held by communication with the above-mentioned authentication program at the authentication information maintenance means 18 is checked.

[0050] In step 70, if the authentication held at the authentication information maintenance means 18 is effective, it will progress to step 80 and a user program will be performed, and if invalid, starting processing of a user program will be completed.

[0051] in the above-mentioned system, once the authentication program is performing user authentication, a user program will be started -- \*\* -- in order not to perform user authentication, the overlapping time and effort can be saved and it is user-friendly. Except it, it is the same as that of the gestalt of the above-mentioned implementation, and the same operation effectiveness is done so.

[0052] In addition, although a series of routines explained actuation of the actuation (steps 10-40) which starts a program, the actuation (steps 90-160) which checks starting of a program, the actuation (steps 50-80) which starts a user program with the gestalt of each above-mentioned implementation, it is the meaning included also when performing by being asynchronous by respectively separate execute form.

[0053] Moreover, although the input of authentication information was performed by entering a password using a keyboard with the gestalt of each above-mentioned implementation, it cannot limit to this and recognition equipments, such as ID cards, such as a magnetic card and an IC card, and a fingerprint, a voiceprint, a retina, can also perform.

[0054] Moreover, in the gestalt of each above-mentioned implementation, a chemical is the meaning which is not limited to drugs and contains various kinds of chemicals, health food including agricultural chemicals, a food additive, and skin external preparations, etc.

[0055] Moreover, the above-mentioned system is applicable to the mutagenicity test before going into the toxicity test of the chemical which used the animal as a living body, and a safety pharmacology study and the safety test by the animal, a drug effect pharmacological test, a general pharmacological test, a drug dynamic body trial, or the clinical trial that medicates the body with a chemical. Moreover, applying to the trial of non-GLP is also possible. The same operation effectiveness is done so also by these cases.

[0056] Moreover, although the gestalt of each above-mentioned implementation showed the example which applied the program selection starter system of this invention to the chemical test-data trial system, it cannot limit to this and can apply to various kinds of operating managerial systems, such as a production control system, an order-received managerial system, a customer management system, and a sales managerial system, etc. The same operation effectiveness is done so also by these cases.

[0057]

[Effect of the Invention] As mentioned above, since two or more programs by which functional partition was carried out for every data item and/or actuation exist independently according to the program selection starter system of this invention, when version up etc. suits a part of programs, if the check of only the program of operation is performed, it will come to end. Therefore, the check of operation after systems

operation initiation can be ensured, and GLP etc. can be guaranteed now. Moreover, since the low unnecessary program of possibility of using it ends even if it does not introduce it, it can also reduce the introductory cost and employment cost of a system sharply.

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TECHNICAL FIELD

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[Field of the Invention] weight, the amount of baiting, the amount of water intakes, biochemical inspection, and clinical manifestation observation of the living body at the time of this invention mainly medicating a living body with a chemical -- it is related with the program selection starter system which can apply - pathological findings, urine volume, ophthalmology-inspection, hemology-inspection, etc. to the chemical trial data control which records, manages and totals.

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**PRIOR ART**

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[Description of the Prior Art] In addition to this, checking them by the nonclinical test which uses animals, such as a rat and a mouse, before drugs, agricultural chemicals and a food additive, and safeties to the body, such as carcinogenic, toxicity, etc. of a chemical, go into a clinical trial although a clinical trial is performed in advance of marketing is performed.

[0003] Safety tests, such as a chemical which used such an animal The single-dose toxicity study to which toxicity will occur if a medicine is prescribed for the patient how much per time, and the toxic description clarifies something, The repeated-dose toxicity study which clarifies the dosage and the toxic description that the dosage and a toxic change to which toxicity sees and is stopped at the time of repeated-dose administration see, and are not stopped, The reproduction test which clarifies effect affect reproduction of a parent animal, effect about next-generation generating, etc., The mutagenicity test which clarifies existence of the property which induces the matter which shows trauma nature to DNA, and mutation is begun, and various kinds of trials, such as a carcinogenicity test, a skin sensitization test, skin photosensitization study, and dependence study, are performed.

[0004] Each above-mentioned trial actually medicates an animal with a chemical, and is performed by totaling and analyzing the data which extracted by performing measurement of an amount, observation, a pathology organization view of a clinical manifestation, etc. of weight, food, water, urine, etc.

[0005] Since such a safety test is performed in advance of the clinical trial which actually medicates the body with the chemical and performs it and the body is finally affected, it is necessary to understand correctly the effect a chemical affects a living body, and to analyze it. For this reason, the computer system has been used for record, and management and analysis of data from the former.

[0006] As mentioned above, since chemicals including drugs are what affects the body, severe criteria are prepared in the data control of the above safety tests in each government office including the Ministry of Health and Welfare so that an alteration may not be added to data. Such a standard is named generically, and is called "GLP (Good Laboratory Practice)", and the computer system which manages data with a natural thing also needs to fulfill the standard of GLP.

[0007] And although it cannot be overemphasized that the design of a system itself needs to conform to GLP, since know-how with a commercial scene very peculiar at a niche is required, as for the above-mentioned system, application of the system concerned serves as a large sum very much. Moreover, when a system is introduced, it needs of operation to be checked at the time of the installation which checks whether GLP is suited and it operates certainly. Moreover, also after operation of a system is started, when some systems have version up, it must check suiting GLP and operating certainly again about the whole system, must leave as a document, and must guarantee that there is no alteration in the system itself.

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[Translation done.]

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**EFFECT OF THE INVENTION**

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[Effect of the Invention] As mentioned above, since two or more programs by which functional partition was carried out for every data item and/or actuation exist independently according to the program selection starter system of this invention, when version up etc. suits a part of programs, if the check of only the program of operation is performed, it will come to end. Therefore, the check of operation after systems operation initiation can be ensured, and GLP etc. can be guaranteed now. Moreover, since the low unnecessary program of possibility of using it ends even if it does not introduce it, it can also reduce the introductory cost and employment cost of a system sharply.

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## TECHNICAL PROBLEM

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[Problem(s) to be Solved by the Invention]

[0009] However, in the conventional system, all functions serve as a package, installation and employment of are done, and GLP etc. is guaranteed with the whole package. For this reason, even when the function of some systems had version up etc., the whole system had to perform the check of operation again. In order that the staff of 2 - trinomial may usually take the time amount for three months or more to such a check of operation, the actual condition is that the check of operation by the bug correction or functional rise after systems operation initiation was not performed at all substantially. And in the system by which all functions were package-ized, many functions in which it is hardly used are added like before, and it had become the factor which pulls up system-wide cost.

[0010] Moreover, in the conventional system, in order to work as it is until it terminates a system, even if an input person etc. has modification on the way after that although a user is attested at the time of starting of a system, decision of an input person was not completed substantially, but when guaranteeing GLP etc., there was a problem.

[0011] This invention was made in view of such a situation, and the check of operation in systems operation is easy, and aims it at the system distribution which is program selection starter system [ low cost moreover ], and can unify authentication.

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[Translation done.]

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MEANS

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[Means for Solving the Problem] In order to attain the above-mentioned purpose, the program selection starter system of this invention The program storing section which stores two or more programs by which functional partition was carried out for every data item and/or actuation, A starting means chosen among the programs by which registration of two or more above-mentioned programs was registered and carried out [ above-mentioned ] to start one of programs at least, It carries out having a program selection means to choose the program which desires starting from the list of the programs displayed on a display means to display the list of the programs registered into the above-mentioned starting means, and the above-mentioned display means as the 1st summary.

[0013] Moreover, the program selection starter system of this invention It is the program selection starter system used for the chemical trial data control which manages data, such as symptom change of the living body at the time of medicating a living body with a chemical. The program storing section which stores two or more programs by which functional partition was carried out for every data item and/or actuation, A starting means chosen among the programs by which registration of two or more above-mentioned programs was registered and carried out [ above-mentioned ] to start one of programs at least, It carries out having a program selection means to choose the program which desires starting from the list of the programs displayed on a display means to display the list of the programs registered into the above-mentioned starting means, and the above-mentioned display means as the 2nd summary.

[0014] Namely, the program selection starter system of this invention The program storing section which stores two or more programs by which functional partition was carried out for every data item and/or actuation, A starting means chosen among the programs by which registration of two or more above-mentioned programs was registered and carried out [ above-mentioned ] to start one of programs at least, It has a program selection means to choose the program which desires starting from the list of the programs displayed on a display means to display the list of the programs registered into the above-mentioned starting means, and the above-mentioned display means. Thus, since two or more programs by which functional partition was carried out for every data item and/or actuation exist independently, when a part of programs have version up etc., if the check of only the program of operation is performed, it will come to end. Therefore, the check of operation after systems operation initiation can be ensured, and GLP etc. can be guaranteed now. Moreover, since the low unnecessary program of possibility of using it ends even if it does not introduce it, it can also reduce the introductory cost and employment cost of a system sharply.

[0015] A seizing acknowledgment means to check whether either is continue starting in the program selection starter system of this invention among the programs by which starting was carried out [ above-mentioned ] for every predetermined time, When it has a user authentication means to ask for the input of a user's authentication information for every predetermined period while starting of one of programs is continuing being checked by the above-mentioned seizing acknowledgment means Since a user is attested for every predetermined period while either of the started programs is continuing starting, an input person etc. can be decided substantially and GLP etc. can be guaranteed certainly.

[0016] In the program selection starter system of this invention, since a variety of [ the toxicity test of the chemical which used the animal as a living body / that it is huge and ] data exist and the class of required data changes with users in many cases in being what is used for the toxicity test of the chemical using the animal as a living body, only the required high program of possibility of using it can be introduced, and system-wide cost can be reduced sharply. Moreover, since two or more observers can perform a data input etc. by turns, the effectiveness of this invention which an input person etc. can check for every fixed period is remarkable,

and effective.

[0017] When the registered program is started in the program selection starter system of this invention, the above-mentioned program checks starting of a user authentication means. When the user authentication means is not started, in starting a user authentication means Since it becomes unnecessary to attest a user while one of programs is started, since authentication of two or more programs with one user authentication means is manageable whenever it starts other programs, working efficiency improves. Moreover, since a user authentication means is not started in program executions other than the registered program, memory space is not consumed beyond the need, therefore the evil of execution speed falling does not arise.

[0018] In the program selection starter system of this invention, it has an authentication information maintenance means to hold the effectiveness information on the user authentication by the user authentication means. It is based on the effectiveness information held for the above-mentioned authentication information maintenance means on the occasion of starting of each program. In order not to perform user authentication for every program starting if user authentication is effective in starting program execution when authentication is effective, and starting program execution, when authentication is invalid, the overlapping time and effort can be saved and it is user-friendly.

[0019]

[Embodiment of the Invention] Below, the gestalt of operation of this invention is explained in detail.

[0020] Drawing 1 is the system configuration Fig. showing the gestalt of 1 operation of the program selection starter system of this invention. This system is what shows the example which applied this invention to the chemical trial data management system. A data input means 1 to input data, such as an amount of the weight when actually medicating an animal with a chemical, food, water, urine, etc., biochemical inspection, hemology-inspection, observation of a clinical manifestation, and various kinds of pathological findings, The data inputted into this data input means 1 were received, and it has a program execution means 2 to perform each program which mentions later and to perform the total of data etc.

[0021] Moreover, an output means (for example, printer) 3 to output to a document etc. the data to which the total etc. was carried out with the above-mentioned program execution means 2, and a display means (for example, display) 4 to display various kinds of information at the time of a data input and data output etc. are formed in the above-mentioned system. Furthermore, it has the data storage section 6 which stores the inputted data via the program execution means 2. In drawing, 12 is storage, such as a hard disk and MO, and 13 is the computer apparatus equipped with a central processing unit, memory, etc.

[0022] Here, processing of the usual data input, a total, etc. is performed by each means which mentioned the above-mentioned system above. That is, the data inputted with the data input means 1 are stored in the data storage section 6 through the program execution means 2, and required information besides the inputted data is displayed by the display means 4 during an input. Moreover, when the total of input data etc. is performed, the totaled data are outputted from the output means 3, and required information besides the data outputted is displayed on the display means 4.

[0023] And the above-mentioned system is equipped with the program storing section 5 which stores two or more programs. Two or more programs by which functional partition was carried out for every data item and/or actuation, such as an output of the total and pathological findings of the input and pathological findings of the output and pathological findings of the total data of the total and weight of the input and weight of weight, are stored in the above-mentioned program storing section 5. The program stored in the above-mentioned program storing section 5 can be introduced now at any time with the program installation means (for example, CD-ROM drive etc.) 14.

[0024] Moreover, each program stored in the above-mentioned program storing section 5 was registered into the above-mentioned system, and equips it with a program starting means 7 to start the program chosen by the user among the programs by which registration was carried out [ above-mentioned ]. Moreover, the correlation means 17 which associates the storing location of each program in the program storing section 5 and the registration location of the program to the program starting means 7 is established.

[0025] Furthermore, the list of the programs registered into the above-mentioned program starting means 7 has a program selection means 8 to choose the program whose user desires starting from the list of the programs which were displayed on the display means 4 and displayed on the above-mentioned display means 4.

[0026] Using input means, such as a mouse, the program of the request which wishes to start is chosen from

the program lists displayed on the menu 14 displayed on Screen 16 of the display means 4, and selection of the program by the above-mentioned program selection means 8 is performed by doubling and clicking the pointer (not shown) of a mouse to the icon 15, as shown in drawing 2 . In addition, a program may be started only one and may start two or more.

[0027] And the program chosen with the program selection means 8 is started by the program starting means 7 based on the correlation information by the correlation means 17. Starting of a program reads a program from the program storing section 5 in memory, develops, and is performed by acquiring activation authority from operation system. And the program started by the program execution means 2 is performed.

[0028] Furthermore, a seizing acknowledgment means 9 to check whether it is started with the program starting means 7, and the program currently performed with the program execution means 2 is continue being started to every predetermined time (for example, 5 minutes) is formed in the above-mentioned system. This seizing acknowledgment actuation is performed by asking operation system whether the program is developed and performed on memory.

[0029] Moreover, while starting of one of programs is continuing being checked by the above-mentioned seizing acknowledgment means 9, a user authentication means 10 to ask every predetermined period (for example, 30 minutes) for the input of a user's authentication information is established. Furthermore, according to the demand of the authentication information input of the above-mentioned user authentication means 10, an authentication information input means 11 to input authentication information is established. Here, the period (authentication time amount) which requires the input of authentication information is set up for a long time than the time amount (seizing acknowledgment time amount) which checks starting of a program.

[0030] The demand of the above-mentioned authentication information input is performed by displaying the password input screen which urges the input of a password to the display means 4. Moreover, the input of authentication information is performed by entering a password into the above-mentioned password input screen using a keyboard.

[0031] Furthermore, the above-mentioned seizing acknowledgment means 9 is started by the above-mentioned program, if the above-mentioned program checks starting of an authentication program (user authentication means 10) and the seizing acknowledgment means 9 is not started, when the program registered into the program starting means is started. Since it becomes unnecessary to attest users, such as a password input, while one of programs is started, since authentication of two or more programs with one user authentication means 10 is manageable by doing in this way whenever it starts other programs, working efficiency improves. Moreover, since the seizing acknowledgment means 9 is not started in program executions other than the registered program, memory space is not consumed beyond the need and the evil of execution speed falling does not arise.

[0032] Below, actuation of the above-mentioned chemical trial data management system is explained based on the flow chart shown in drawing 3 . In addition, in drawing, "S" means a step.

[0033] First, the list of the programs registered is displayed on the display means 4 by starting a launcher program (program starting means 7) (S10: refer to drawing 2 ). Subsequently, out of the menu 14 displayed on Screen 16 of the display means 4, it clicks on the icon 15 of the program for which it asks, a desired program is chosen (S20), and a program is started (S30). At this time, if starting of an authentication program (seizing acknowledgment means 9) is checked and the seizing acknowledgment means 9 is not started by the program by which starting was carried out [ above-mentioned ], the seizing acknowledgment means 9 is started by the above-mentioned program (S70).

[0034] And if it is necessary to start the program of further others and return (S40) and its need will not be in step 1, the started program will be performed and processing according to each program, such as data inputs of weight, food, water, urine, etc., such as an amount and an observation view of a pathology symptom, and a total of input data, a document output of total data, will be performed (S50). And if there is the need for an activity succeedingly and return and its need will not be in step 10, it will end (S60).

[0035] On the other hand, it checks whether when waiting (S80) and the above-mentioned seizing acknowledgment time amount always pass, the program has started the progress of seizing acknowledgment time amount (for example, 5 minutes) which checks whether the program which continued starting an authentication program in parallel to the above-mentioned processing, and was started with the program starting means 7 has started (S90).

[0036] Subsequently, if one of programs has started (S100), it will wait for progress of the authentication time

amount (for example, 30 minutes) which attests a user (S110). If the above-mentioned authentication time amount has not passed, return and the actuation which waited for and mentioned above the seizing acknowledgment passage of time again are repeated to step 80.

[0037] In step 110, progress of authentication time amount requires the input of authentication information of a user by directing a halt of activation to two or more programs performed now, and displaying a password input screen on the display means 4 at the time, etc. (S120). And if authentication information, such as an exact password, is inputted, while directing the restart of activation to the program which is in a halt condition, return and the actuation mentioned above are again repeated to step 8 (S130).

[0038] If authentication information is not inputted, it returns to step 120 and the input of authentication information is required again -- on the other hand in step 130, the entered password is mistaken. And even if it repeats the number of regularity times, when an exact password is not entered and a user's authentication is not completed, to the program which is in a halt condition, forced termination of activation is directed and a program is ended in response to termination directions.

[0039] On the other hand, if all the programs started with the program starting means 7 are completed in step 100, it will end. Thus, since a user is attested for every predetermined period while either of the started programs is continuing starting, an input person can decide substantially and GLP etc. can be guaranteed certainly.

[0040] Thus, since two or more programs by which functional partition was carried out for every data item and/or actuation exist independently according to the above-mentioned system, when a part of programs have version up etc., if the check of only the program of operation is performed, it will come to end. Therefore, the check of operation after systems operation initiation can be ensured, and GLP etc. can be guaranteed now. Moreover, since the low unnecessary program of possibility of using it ends even if it does not introduce it, it can also reduce system-wide cost sharply.

[0041] The above-mentioned system is used suitable for the toxicity test of the chemical which used the animal as a living body. It is because a variety of [ the above-mentioned toxicity test / that it is huge and ] data exist, the class of required data changes with users in many cases, so only the required high program of possibility of using it can be introduced and system-wide cost can be reduced sharply. Moreover, it is because two or more observers perform a data input etc. by turns in many cases, so the effectiveness of this invention which an input person etc. can check for every fixed period is remarkable and effective.

[0042] Drawing 4 is the system configuration Fig. showing the gestalt of operation of the 2nd of this invention.

[0043] The user program by which this system is performed with a program execution means starts an authentication program (user authentication means 10). Moreover, it judges whether it has an authentication information maintenance means 18 to hold the authentication information concerning effective/invalid of authentication by the user authentication means 10, a user program communicates with an authentication program, and the above-mentioned system continues activation of the user program itself. Furthermore, itself judges termination so that itself may not start an authentication program repeatedly. The same sign is given to the part that it is the same as that of the gestalt of implementation of the above 1st, and same except it.

[0044] Drawing 5 is a flow chart which shows actuation of the above-mentioned system. In addition, in drawing, "S" means a step.

[0045] That is, the list of the programs registered is first displayed on the display means 4 by starting a launcher program (program starting means 7) (S10: refer to drawing 2 ). Subsequently, if it clicks on the icon 15 of the program for which it asks and a desired user program is chosen out of the menu 14 displayed on Screen 16 of the display means 4 (S20), starting of a user program will be started (S30). And to step 10, when not ending a launcher program, return and when that is not right, it ends (S40).

[0046] If starting of a user program is started in step 30, starting of an authentication program (seizing acknowledgment means 9) will be started (S50). If an authentication program is started, if it has already performed, in order to prevent double starting, it will progress to step 90, and the check of whether the authentication program has already been performed is performed, and if starting actuation of an authentication program is not performed, it will progress [ it ends, and ] to step 100.

[0047] Step 100 requires the input of authentication information, such as a password and user ID, from the authentication information input means 11. At step 110, the password and user ID which were inputted in step 100 judge whether it is it is just and effective or invalid. In step 110, if authentication is effective, the authentication owner effect will be notified to a user program, and the information on the authentication owner

effect will be held for the authentication information maintenance means 18 (S115). On the other hand, if authentication is invalid in step 110, an authentication invalid will be notified to a user program and the information on an authentication invalid will be held for the authentication information maintenance means 18 (S120).

[0048] Subsequently, if the above-mentioned authentication time amount has not passed progress of the authentication time amount (for example, 30 minutes) which attests a user in waiting (S130) and step 140, return and the actuation which waited for and mentioned the authentication passage of time above again are repeated to step 130. If authentication time amount has passed in step 140, it will check whether the user program is performed (S150). And if the user program is performed at least one in step 160, return and the actuation which waited for and mentioned the authentication passage of time above again will be repeated to step 130. An authentication program is ended if one is not performed for the user program in step 160.

[0049] On the other hand, after starting of a user program is started in step 30 and starting of an authentication program is started in step 50, it progresses to step 60 and information concerning effective/invalid of the authentication held by communication with the above-mentioned authentication program at the authentication information maintenance means 18 is checked.

[0050] In step 70, if the authentication held at the authentication information maintenance means 18 is effective, it will progress to step 80 and a user program will be performed, and if invalid, starting processing of a user program will be completed.

[0051] in the above-mentioned system, once the authentication program is performing user authentication, a user program will be started -- \*\* -- in order not to perform user authentication, the overlapping time and effort can be saved and it is user-friendly. Except it, it is the same as that of the gestalt of the above-mentioned implementation, and the same operation effectiveness is done so.

[0052] In addition, although a series of routines explained actuation of the actuation (steps 10-40) which starts a program, the actuation (steps 90-160) which checks starting of a program, the actuation (steps 50-80) which starts a user program with the gestalt of each above-mentioned implementation, it is the meaning included also when performing by being asynchronous by respectively separate execute form.

[0053] Moreover, although the input of authentication information was performed by entering a password using a keyboard with the gestalt of each above-mentioned implementation, it cannot limit to this and recognition equipments, such as ID cards, such as a magnetic card and an IC card, and a fingerprint, a voiceprint, a retina, can also perform.

[0054] Moreover, in the gestalt of each above-mentioned implementation, a chemical is the meaning which is not limited to drugs and contains various kinds of chemicals, health food including agricultural chemicals, a food additive, and skin external preparations, etc.

[0055] Moreover, the above-mentioned system is applicable to the mutagenicity test before going into the toxicity test of the chemical which used the animal as a living body, and a safety pharmacology study and the safety test by the animal, a drug effect pharmacological test, a general pharmacological test, a drug dynamic body trial, or the clinical trial that medicates the body with a chemical. Moreover, applying to the trial of non-GLP is also possible. The same operation effectiveness is done so also by these cases.

[0056] Moreover, although the gestalt of each above-mentioned implementation showed the example which applied the program selection starter system of this invention to the chemical test-data trial system, it cannot limit to this and can apply to various kinds of operating managerial systems, such as a production control system, an order-received managerial system, a customer management system, and a sales managerial system, etc. The same operation effectiveness is done so also by these cases.

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[Translation done.]

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**DESCRIPTION OF DRAWINGS**

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[Brief Description of the Drawings]

[Drawing 1] It is the system configuration Fig. showing the gestalt of 1 operation of the program selection starter system of this invention.

[Drawing 2] It is drawing showing an example of the display screen by the program starting means.

[Drawing 3] It is a flow chart Fig. explaining actuation of the above-mentioned program selection starter system.

[Drawing 4] It is the system configuration Fig. showing the program selection starter system of the gestalt of operation of the 2nd of this invention.

[Drawing 5] It is a flow chart Fig. explaining actuation of the above-mentioned program selection starter system.

[Description of Notations]

4 Display Means

5 Program Storing Section

7 Program Starting Means

8 Program Selection Means

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[Translation done.]

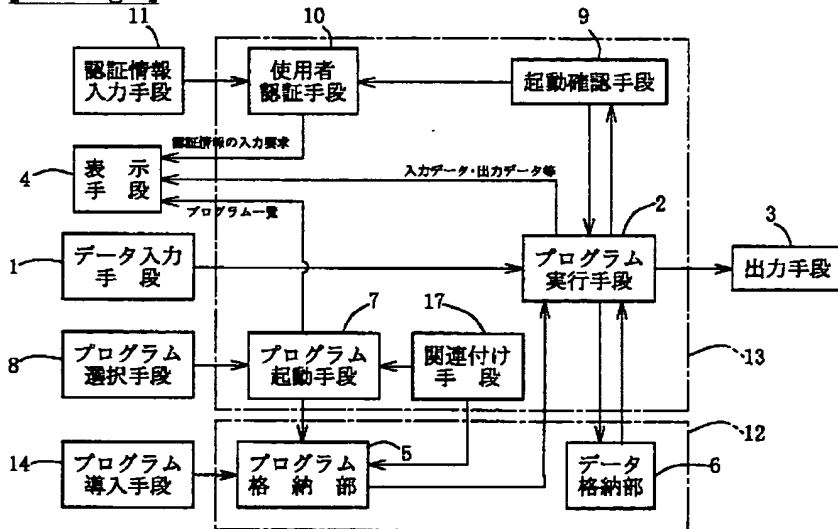
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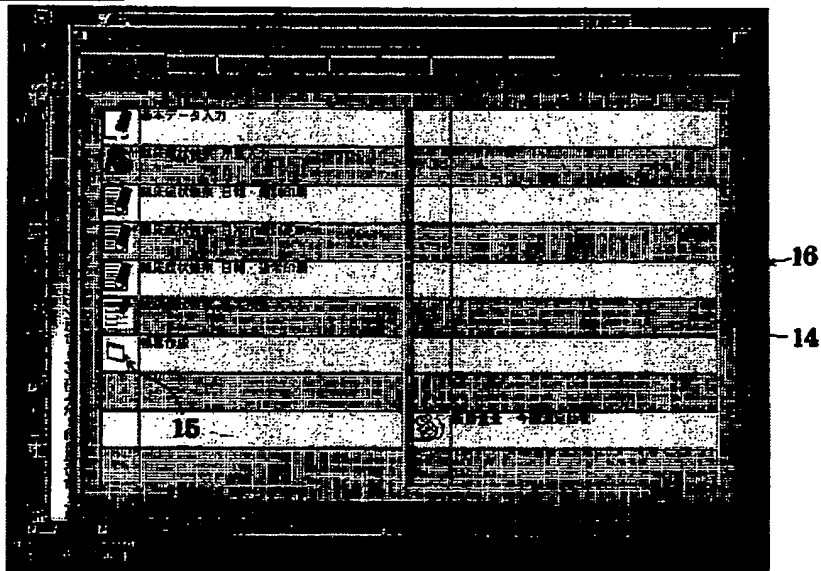
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## DRAWINGS

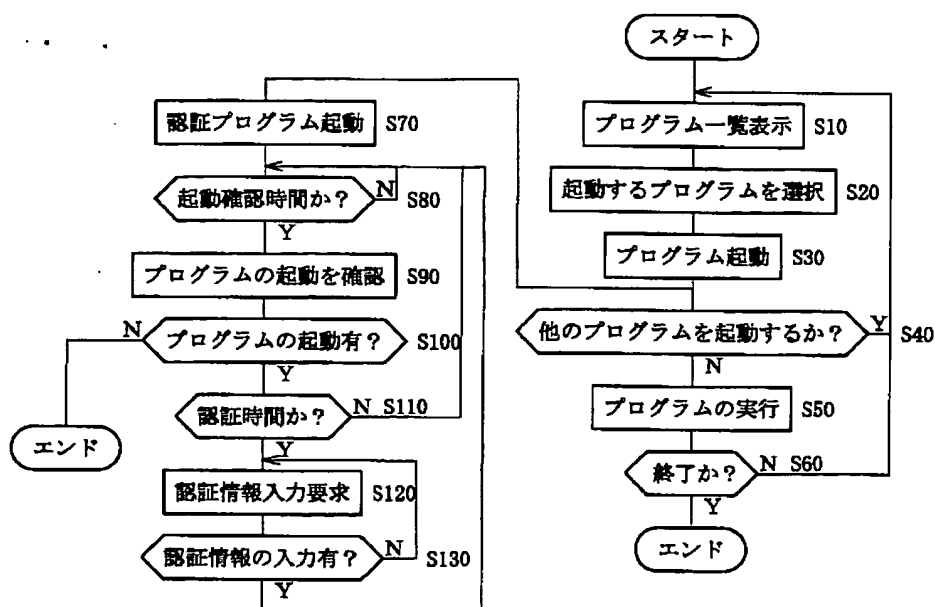
[Drawing 1]



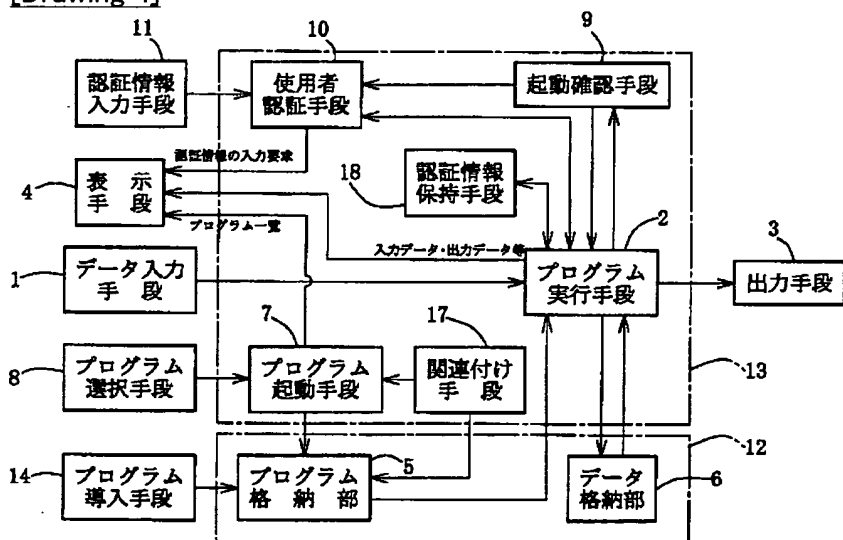
[Drawing 2]



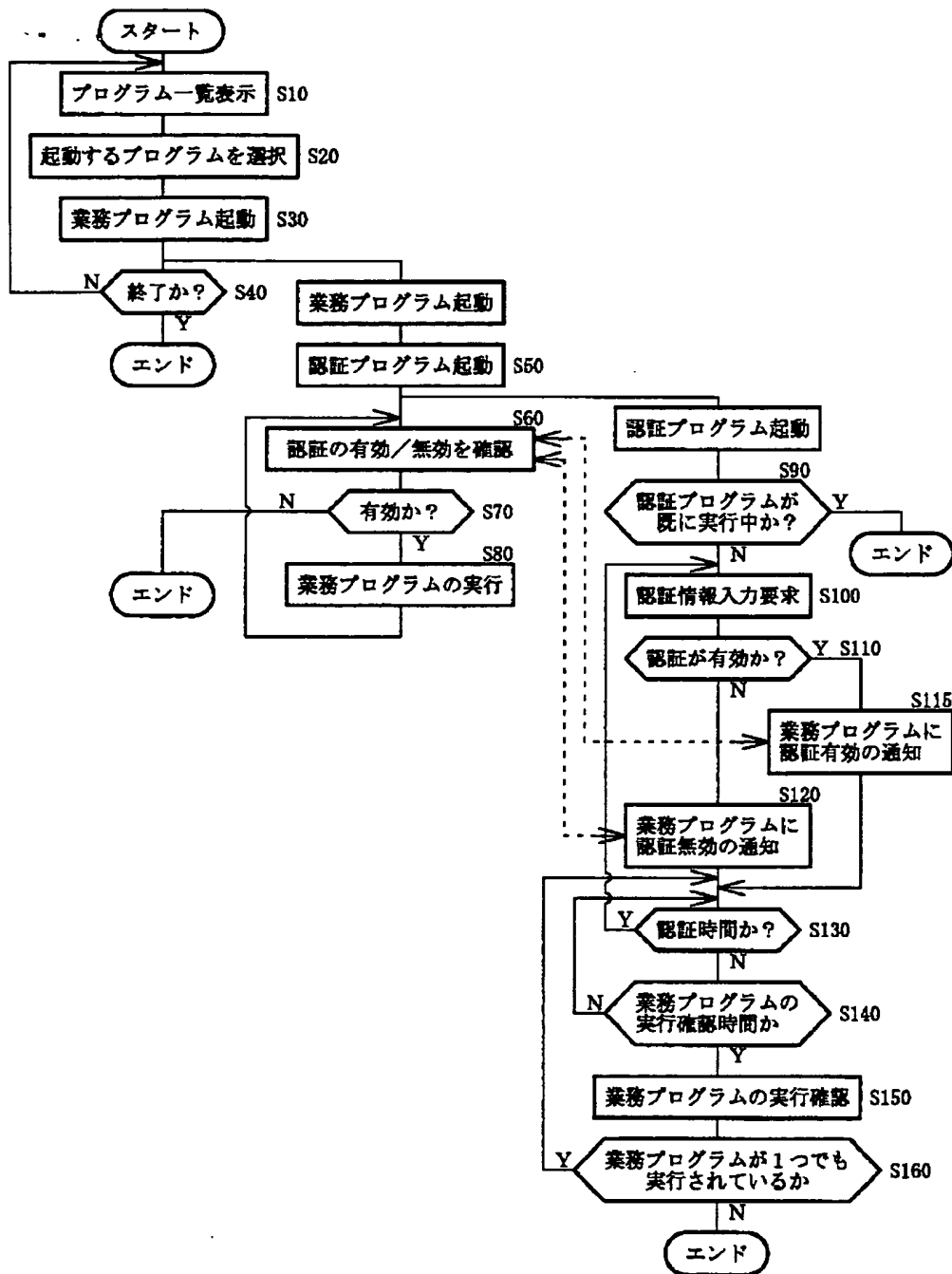
[Drawing 3]



[Drawing 4]



[Drawing 5]



[Translation done.]

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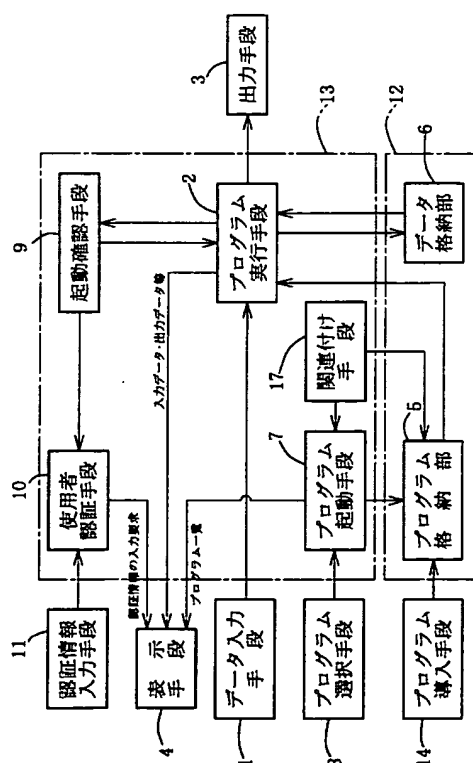
Fターム(参考) 5B076 FA06 FB02

## (54) 【発明の名称】 プログラム選択起動システム

## (57) 【要約】

【課題】 システム運用中の動作確認が容易で、しかも低コストなプログラム選択起動システムを提供する。

【解決手段】 データ項目および/または操作ごとに機能分割された複数のプログラムを格納するプログラム格納部5と、上記複数のプログラムが登録され上記登録されたプログラムのうち選択されたいずれかのプログラムを起動するプログラム起動手段7と、上記プログラム起動手段7に登録されたプログラム一覧を表示する表示手段4と、これらに表示されたプログラム一覧から起動を望むプログラムを選択するプログラム選択手段8とを備えたことにより、システム運用開始後等に一部のプログラムだけの動作確認を確実に行ってG L P等を保証でき、不要なプログラムは導入しなくてすむためコストが低下する。



## 【特許請求の範囲】

【請求項1】 データ項目および／または操作ごとに機能分割された複数のプログラムを格納するプログラム格納部と、上記複数のプログラムが登録され上記登録されたプログラムのうち選択された少なくともいずれかのプログラムを起動する起動手段と、上記起動手段に登録されたプログラムの一覧を表示する表示手段と、上記表示手段に表示されたプログラムの一覧から起動を望むプログラムを選択するプログラム選択手段とを備えていることを特徴とするプログラム選択起動システム。

【請求項2】 薬品を生体に投与した際の生体の症状変化等のデータを管理する薬品試験データ管理に用いられるプログラム選択起動システムであって、データ項目および／または操作ごとに機能分割された複数のプログラムを格納するプログラム格納部と、上記複数のプログラムが登録され上記登録されたプログラムのうち選択された少なくともいずれかのプログラムを起動する起動手段と、上記起動手段に登録されたプログラムの一覧を表示する表示手段と、上記表示手段に表示されたプログラムの一覧から起動を望むプログラムを選択するプログラム選択手段とを備えていることを特徴とするプログラム選択起動システム。

【請求項3】 上記起動されたプログラムのうちいずれかが起動し続けているか否かを所定時間ごとに確認する起動確認手段と、上記起動確認手段によりいずれかのプログラムの起動が確認され続けている間、所定期間ごとに使用者の認証情報の入力を求める使用者認証手段とを備えている請求項1または2記載のプログラム選択起動システム。

【請求項4】 生体として動物を用いた薬品の毒性試験に用いられるものである請求項1～3のいずれか一項に記載のプログラム選択起動システム。

【請求項5】 使用者認証手段による使用者認証の有効性情報を保持する認証情報保持手段を備え、各プログラムの起動の際に、上記認証情報保持手段に保持された有効性情報に基づいて、認証が有効な場合にプログラムの実行を開始し、認証が無効な場合にプログラムの実行を開始しないようになっている請求項3または4記載のプログラム選択起動システム。

## 【発明の詳細な説明】

## 【0001】

【発明の属する技術分野】本発明は、主として薬品を生体に投与した際の生体の体重・摂餌量・摂水量・生化学検査・臨床症状観察・病理所見・尿量・眼科学的検査・血液学的検査等を記録・管理・集計する薬品試験データ管理等に適用可能なプログラム選択起動システムに関するものである。

## 【0002】

【従来の技術】医薬品・農薬・食品添加物・その他化学物質の発癌性や毒性等、人体に対する安全性は、市販に

先だって臨床試験が行われるが、臨床試験に入る前に、ラットやマウス等の動物を使用する非臨床試験で確認することが行われている。

【0003】このような動物を使用した薬品等の安全性試験は、1回あたりどの程度投与すれば毒性が発生し、その毒性の特徴が何かを明らかにする単回投与毒性試験、反復投与時に毒性が見とめられる用量と毒性変化が見とめられない用量および毒性の特徴を明らかにする反復投与毒性試験、親動物の生殖に及ぼす影響や次世代の発生に関する影響等を明らかにする生殖・発生毒性試験、DNAに傷害性を示す物質や突然変異を誘発する性質の有無を明らかにする変異原性試験をはじめ、癌原性試験、皮膚感作性試験、皮膚光感作性試験、依存性試験等の各種の試験が行われる。

【0004】上記各試験は、薬品を実際に動物に投与し、体重、餌、水、尿等の量の測定や臨床症状の観察・病理組織所見等を行い、採取したデータを集計し、分析することによって行われる。

【0005】このような安全性試験は、その薬品を実際に人体に投与して行う臨床試験に先立って行われ、最終的には人体に影響を及ぼすものであることから、薬品が生体に及ぼす影響を正確に理解し、分析することが必要になる。このため、データの記録や管理・分析には、従来からコンピュータシステムが用いられてきた。

【0006】上述したように、医薬品をはじめとする薬品は、人体に影響を与えるものであるため、上記のような安全性試験のデータ管理には、データに改ざんが加えられることのないよう、厚生省をはじめとする各官庁で厳しい基準が設けられている。このような規準は、総称して「GLP (Good Laboratory Practice)」と呼ばれ、当然のことながら、データを管理するコンピュータシステムもGLPの規準を満たしている必要がある。

【0007】そして、上記システムは、システムの設計自体がGLPに適合している必要があるのは言うまでもないが、当該システムの適用が、非常に市場がニッチで独特のノウハウが必要なため、非常に高額となる。また、システムを導入した際に、GLPに適合して確実に動作するか否かを確認する導入時の動作確認が必要である。また、システムの運用が開始されてからも、システムの一部にバージョンアップがあったような場合には、GLPに適合して確実に動作することをシステム全体について再度確認して文書として残し、システム自体にも改ざんがないことを保証しなければならない。

## 【0008】

【発明が解決しようとする課題】

【0009】しかしながら、従来のシステムでは、全ての機能がパッケージとなって導入・運用され、パッケージ全体でGLP等を保証するようになっている。このため、システムの一部の機能にバージョンアップ等があっ

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た場合でも、再度システム全体で動作確認を行わなければならなかった。このような動作確認は、通常2〜3名の人員で3ヶ月以上の時間を要するため、システム運用開始後のバグ修正や機能アップによる動作確認は、実質的には全く行われていなかったのが実情である。しかも、従来のように全ての機能がパッケージ化されたシステムでは、ほとんど使用されることのない機能が数多く付加されており、システム全体のコストを引き上げる要因となっていた。

【0010】また、従来のシステムでは、システムの起動時に使用者の認証を行うものの、その後は途中で入力者等に変更があってもシステムを終了させるまでそのまま稼動されるため、実質的に入力者の確定ができておらず、G L P等を保証する上で問題があった。

【0011】本発明は、このような事情に鑑みなされたもので、システム運用中の動作確認が容易で、しかも低コストなプログラム選択起動システムでかつ、認証を一本化可能なシステムの提供を目的とする。

【0012】

【課題を解決するための手段】上記の目的を達成するため、本発明のプログラム選択起動システムは、データ項目および／または操作ごとに機能分割された複数のプログラムを格納するプログラム格納部と、上記複数のプログラムが登録され上記登録されたプログラムのうち選択された少なくともいずれかのプログラムを起動する起動手段と、上記起動手段に登録されたプログラムの一覧を表示する表示手段と、上記表示手段に表示されたプログラムの一覧から起動を望むプログラムを選択するプログラム選択手段とを備えていることを第1の要旨とする。

【0013】また、本発明のプログラム選択起動システムは、薬品を生体に投与した際の生体の症状変化等のデータを管理する薬品試験データ管理に用いられるプログラム選択起動システムであって、データ項目および／または操作ごとに機能分割された複数のプログラムを格納するプログラム格納部と、上記複数のプログラムが登録され上記登録されたプログラムのうち選択された少なくともいずれかのプログラムを起動する起動手段と、上記起動手段に登録されたプログラムの一覧を表示する表示手段と、上記表示手段に表示されたプログラムの一覧から起動を望むプログラムを選択するプログラム選択手段とを備えていることを第2の要旨とする。

【0014】すなわち、本発明のプログラム選択起動システムは、データ項目および／または操作ごとに機能分割された複数のプログラムを格納するプログラム格納部と、上記複数のプログラムが登録され上記登録されたプログラムのうち選択された少なくともいずれかのプログラムを起動する起動手段と、上記起動手段に登録されたプログラムの一覧を表示する表示手段と、上記表示手段に表示されたプログラムの一覧から起動を望むプログラムを選択するプログラム選択手段とを備えている。この

ように、データ項目および／または操作ごとに機能分割された複数のプログラムが独立して存在するため、例えば、一部のプログラムにバージョンアップ等があったような場合、そのプログラムだけの動作確認を行えばすむようになる。したがって、システム運用開始後の動作確認を確実に行ってG L P等を保証することができるようになる。また、使用する可能性の低い不要なプログラムは導入しなくてもすむため、システムの導入コストや運用コストを大幅に引き下げることができる。

【0015】本発明のプログラム選択起動システムにおいて、上記起動されたプログラムのうちいずれかが起動し続けているか否かを所定時間ごとに確認する起動確認手段と、上記起動確認手段によりいずれかのプログラムの起動が確認され続けている間、所定期間ごとに使用者の認証情報の入力を求める使用者認証手段とを備えている場合には、起動されたプログラムのいずれかが起動しつづけている間、所定期間ごとに使用者の認証を行うため、実質的に入力者等が確定でき、確実にG L P等を保証することができる。

【0016】本発明のプログラム選択起動システムにおいて、生体として動物を用いた薬品の毒性試験に用いられるものである場合には、生体として動物を用いた薬品の毒性試験が、膨大で多種多様なデータが存在し、ユーザーによって必要なデータの種類の異なることが多いため、使用する可能性の高い必要なプログラムだけ導入でき、システム全体のコストを大幅に引き下げることができる。また、複数の観察者が交代でデータ入力等を行うこともありうるため、一定期間ごとに入力者等が確認できる本発明の効果が顕著であり効果的である。

【0017】本発明のプログラム選択起動システムにおいて、登録されたプログラムが起動されたときに上記プログラムが使用者認証手段の起動を確認し、使用者認証手段が起動されていない場合に使用者認証手段を起動させるようになっている場合には、ひとつの使用者認証手段で複数のプログラムの認証を管理できるため、いずれかのプログラムが起動されている間、他のプログラムを起動するたびに使用者の認証を行う必要がなくなるため、作業効率が向上する。また、登録されたプログラム以外のプログラムの実行中に使用者認証手段が起動されないため、必要以上にメモリ容量を消費せず、そのために実行速度が低下する等の弊害が生じない。

【0018】本発明のプログラム選択起動システムにおいて、使用者認証手段による使用者認証の有効性情報を保持する認証情報保持手段を備え、各プログラムの起動の際に、上記認証情報保持手段に保持された有効性情報に基づいて、認証が有効な場合にプログラムの実行を開始し、認証が無効な場合にプログラムの実行を開始しないようになっている場合には、使用者認証が有効であればプログラム起動ごとの使用者認証を行わないため、重複する手間が省けて使い勝手がよい。

【0019】

【発明の実施の形態】つぎに、本発明の実施の形態を詳しく説明する。

【0020】図1は、本発明のプログラム選択起動システムの一実施の形態を示すシステム構成図である。このシステムは、本発明を薬品試験データ管理システムに適用した例を示すものであり、薬品を実際に動物に投与したときの体重、餌、水、尿等の量や生化学検査、血液学的検査、臨床症状の観察、各種の病理所見等のデータを10 入力するデータ入力手段1と、このデータ入力手段1に10 入力されたデータを受信して、後述する各プログラムを実行してデータの集計等を行うプログラム実行手段2とを備えている。

【0021】また、上記システムには、上記プログラム実行手段2で集計等されたデータ等を帳票等に出力する出力手段（例えばプリンタ）3と、データ入力時やデータ出力時等に各種の情報を表示する表示手段（例えばディスプレイ）4とが設けられている。さらに、入力されたデータをプログラム実行手段2を経由して格納するデータ格納部6とを備えている。図において、12はハードディスクやMO等の記憶装置であり、13は中央演算装置およびメモリ等を備えたコンピュータ装置である。

【0022】ここで、上記システムは、上述した各手段により、通常の入力や集計等の処理が行われるようになっている。すなわち、データ入力手段1で入力されたデータは、プログラム実行手段2を介してデータ格納部6に格納され、入力作業中には、入力されたデータの他、必要な情報が表示手段4に表示されるようになっている。また、入力データの集計等を行った場合には、集計されたデータが出力手段3から出力され、出力されるデータの他必要な情報が表示手段4に表示されるようになっている。

【0023】そして、上記システムには、複数のプログラムを格納するプログラム格納部5を備えている。上記プログラム格納部5には、例えば、体重の入力・体重の集計・体重の集計データの出力・病理所見の入力・病理所見の集計・病理所見の出力等、データ項目および／または操作ごとに機能分割された複数のプログラムが格納されている。上記プログラム格納部5に格納されるプログラムは、プログラム導入手段（例えばCD-ROMドライブ等）14によって随時導入しうようになっている。

【0024】また、上記システムには、上記プログラム格納部5に格納された各プログラムが登録され、上記登録されたプログラムのうち使用者によって選択されたプログラムを起動するプログラム起動手段7を備えている。また、プログラム格納部5での各プログラムの格納場所と、プログラム起動手段7へのプログラムの登録場所とを関連付ける関連付け手段17が設けられている。

【0025】さらに、上記プログラム起動手段7に登録

されたプログラムの一覧は、表示手段4に表示されるようになっており、上記表示手段4に表示されたプログラムの一覧から使用者が起動を望むプログラムを選択するプログラム選択手段8を備えている。

【0026】上記プログラム選択手段8によるプログラムの選択は、例えば、マウス等の入力手段を用い、図2に示すように、表示手段4の画面16上に表示されたメニュー14に表示されたプログラム一覧のなかから、起動を希望する所望のプログラムを選び、そのアイコン15にマウスのポインタ（図示せず）を合わせてクリックすることにより行われる。なお、プログラムはひとつだけ起動させてもよいし、ふたつ以上を起動させてもよい。

【0027】そして、プログラム選択手段8で選択されたプログラムは、関連付け手段17による関連付け情報に基づいて、プログラム起動手段7によって起動される。プログラムの起動は、プログラム格納部5からプログラムをメモリ内に読み出して展開し、オペレーションシステムから実行権限を取得することにより行われる。そして、プログラム実行手段2により起動されたプログラムが実行されるようになっている。

【0028】さらに、上記システムには、プログラム起動手段7で起動され、プログラム実行手段2で実行されているプログラムが、起動されつづけているか否かを所定時間（例えば5分）ごとに確認する起動確認手段9が設けられている。この起動確認動作は、プログラムがメモリ上に展開され実行されているかどうかをオペレーションシステムに問合せることにより行われる。

【0029】また、上記起動確認手段9によりいずれかのプログラムの起動が確認され続けている間、所定期間（例えば30分）ごとに使用者の認証情報の入力を求める使用者認証手段10が設けられている。さらに、上記使用者認証手段10の認証情報入力の要求に応じ、認証情報を入力する認証情報入力手段11が設けられている。ここで、認証情報の入力を要求する期間（認証時間）は、プログラムの起動を確認する時間（起動確認時間）よりも長く設定されている。

【0030】上記認証情報入力の要求は、例えば、表示手段4にパスワードの入力を促すパスワード入力画面を表示することにより行われる。また、認証情報の入力は、例えば、キーボードを用いて上記パスワード入力画面にパスワードを入力することにより行われる。

【0031】さらに、上記起動確認手段9は、プログラム起動手段に登録されたプログラムが起動されたときに上記プログラムが認証プログラム（使用者認証手段10）の起動を確認し、起動確認手段9が起動されていないければ、上記プログラムによって起動されるようになっている。このようにすることにより、ひとつの使用者認証手段10で複数のプログラムの認証を管理できるため、いずれかのプログラムが起動されている間、他のプ

プログラムを起動するたびにパスワード入力等の使用者の認証を行う必要がなくなるため、作業効率が向上する。また、登録されたプログラム以外のプログラムの実行中に起動確認手段9が起動されないため、必要以上にメモリ容量を消費せず、実行速度が低下する等の弊害が生じない。

【0032】つぎに、上記薬品試験データ管理システムの動作について、図3に示すフローチャートをもとに説明する。なお、図において「S」は、ステップを意味する。

【0033】まず、ランチャープログラム（プログラム起動手段7）を起動することにより、登録されているプログラムの一覧が表示手段4に表示される（S10：図2参照）。ついで、表示手段4の画面16に表示されたメニュー14のなかから、所望するプログラムのアイコン15をクリックして所望のプログラムを選択し（S20）、プログラムを起動させる（S30）。このとき、上記起動されたプログラムにより、認証プログラム（起動確認手段9）の起動が確認され、起動確認手段9が起動されていなければ上記プログラムにより起動確認手段9が起動される（S70）。

【0034】そして、さらに他のプログラムを起動する必要がある場合はステップ1に戻り（S40）、その必要がなければ、起動させたプログラムを実行して、体重、餌、水、尿等の量や病理症状の観察所見等のデータ入力や、入力データの集計、集計データの帳票出力等の各プログラムに応じた処理を行う（S50）。そして、引き続き作業の必要がある場合はステップ10に戻り、その必要がなければ終了する（S60）。

【0035】一方、認証プログラムは、上記処理と並行して起動し続け、プログラム起動手段7で起動されたプログラムが起動しているか否かを確認する起動確認時間（例えば5分）の経過を常時待ち（S80）、上記起動確認時間が経過した時点で、プログラムが起動しているか否かを確認する（S90）。

【0036】ついで、いずれかのプログラムが起動していれば（S100）、使用者の認証を行う認証時間（例えば30分）の経過を待つ（S110）。上記認証時間が経過していなければステップ80に戻り、再度起動確認時間の経過を待つて上述した動作を繰り返す。

【0037】ステップ110において、認証時間が経過すると、その時点で、現在実行されている複数のプログラムに実行の一時停止を指示し、表示手段4にパスワード入力画面を表示する等により、使用者に認証情報の入力要求する（S120）。そして正確なパスワード等の認証情報が入力されると、一時停止状態であるプログラムに対して実行の再開を指示するとともに、再びステップ8に戻り、上述した動作を繰り返す（S130）。

【0038】一方、ステップ130において、入力されたパスワードが誤っている等、認証情報が入力されな

れば、ステップ120に戻り、再び認証情報の入力を要求する。そして、一定回数繰り返しても正確なパスワードが入力されず、使用者の認証ができなかった場合は、一時停止状態であるプログラムに対し、実行の強制終了を指示し、プログラムは終了指示を受けて終了する。

【0039】一方、ステップ100において、プログラム起動手段7で起動したすべてのプログラムが終了していれば終了する。このように、起動されたプログラムのいずれかが起動しつづけている間、所定期間ごとに使用者の認証を行うため、実質的に入力者が確定でき、確実にGLP等を保証することができる。

【0040】このように、上記システムによれば、データ項目および／または操作ごとに機能分割された複数のプログラムが独立して存在するため、一部のプログラムにバージョンアップ等があった場合、そのプログラムだけの動作確認を行えばすむようになる。したがって、システム運用開始後の動作確認を確実に行ってGLP等を保証することができるようになる。また、使用する可能性の低い不要なプログラムは導入しなくてもすむため、システム全体のコストを大幅に引き下げることができ

る。

【0041】上記システムは、生体として動物を用いた薬品の毒性試験に好適に用いられる。上記毒性試験が、膨大で多種多様なデータが存在し、ユーザーによって必要なデータの種類の異なることが多いため、使用する可能性の高い必要なプログラムだけ導入でき、システム全体のコストを大幅に引き下げることができるからである。また、複数の観察者が交代でデータ入力等を行うことが多いため、一定期間ごとに入力者等が確認できる本発明の効果が顕著であり効果的だからである。

【0042】図4は、本発明の第2の実施の形態を示すシステム構成図である。

【0043】このシステムは、プログラム実行手段で実行される業務プログラムが、認証プログラム（使用者認証手段10）を起動するようになっている。また、上記システムは、使用者認証手段10による認証の有効／無効に係る認証情報を保持する認証情報保持手段18を有し、業務プログラムが認証プログラムと通信して業務プログラム自体の実行を継続するか否かを判断するようになっている。さらに、認証プログラムは、それ自体が何度も起動してしまわないように、それ自体が終了を判断するようになっている。それ以外は、上記第1の実施の形態と同様であり同様の部分には同じ符号を付している。

【0044】図5は、上記システムの動作を示すフローチャートである。なお、図において「S」は、ステップを意味する。

【0045】すなわち、まず、ランチャープログラム（プログラム起動手段7）を起動することにより、登録されているプログラムの一覧が表示手段4に表示される

(S10:図2参照)。ついで、表示手段4の画面16に表示されたメニュー14のなかから、所望するプログラムのアイコン15をクリックして所望の業務プログラムを選択すると(S20)、業務プログラムの起動が開始される(S30)。そして、ランチャープログラムを終了しない場合はステップ10に戻り、そうでない場合は終了する(S40)。

【0046】ステップ30において業務プログラムの起動が開始されると、認証プログラム(起動確認手段9)の起動が開始される(S50)。認証プログラムが起動されると、ステップ90に進み、認証プログラムが既に実行されているか否かの確認がおこなわれ、既に実行されていれば2重起動を防止するために認証プログラムの起動動作は終了し、実行されていなければステップ100に進む。

【0047】ステップ100では、認証情報入力手段11に対してパスワードやユーザID等の認証情報の入力を要求する。ステップ110では、ステップ100において入力されたパスワードやユーザIDが正当で有効であるか無効であるかを判断する。ステップ110において、認証が有効であれば、業務プログラムに認証有効の通知を行い、認証情報保持手段18に認証有効の情報を保持する(S115)。一方、ステップ110において、認証が無効であれば、業務プログラムに認証無効の通知を行い、認証情報保持手段18に認証無効の情報を保持する(S120)。

【0048】ついで、使用者の認証を行う認証時間(例えば30分)の経過を待ち(S130)、ステップ140において上記認証時間が経過していなければステップ130に戻り、再度認証時間の経過を待って上述した動作を繰り返す。ステップ140において認証時間が経過していれば業務プログラムが実行されているか否かの確認を行なう(S150)。そして、ステップ160において業務プログラムが1つでも実行されていればステップ130に戻り、再度認証時間の経過を待って上述した動作を繰り返す。ステップ160において業務プログラムが1つも実行されていなければ、認証プログラムを終了する。

【0049】一方、ステップ30において業務プログラムの起動が開始され、ステップ50において認証プログラムの起動が開始されたのち、ステップ60に進み、上記認証プログラムとの交信により認証情報保持手段18に保持された認証の有効/無効に係る情報の確認を行なう。

【0050】ステップ70において、認証情報保持手段18に保持された認証が有効であれば、ステップ80に進み、業務プログラムが実行され、無効であれば業務プログラムの起動処理が終了する。

【0051】上記システムでは、認証プログラムが一旦ユーザ認証を行なっていれば、業務プログラムを起動す

るごとのユーザ認証を行なわないため、重複する手間が省け、使い勝手がよい。それ以外は、上記実施の形態と同様であり、同様の作用効果を奏する。

【0052】なお、上記各実施の形態では、プログラムを起動する動作(ステップ10~40)、プログラムの起動を確認する動作(ステップ90~160)、業務プログラムを起動する動作(ステップ50~80)等の動作を一連のルーチンで説明したが、それぞれ別個の実行形式で非同期で実行される場合も含む趣旨である。

【0053】また、上記各実施の形態では、認証情報の入力を、キーボードを用いてパスワードを入力することにより行ったが、これに限定するものではなく、磁気カードやICカード等のIDカード、指紋・声紋・網膜等の認識装置によって行うこともできる。

【0054】また、上記各実施の形態において、薬品とは、医薬品に限定されるものではなく、農薬、食品添加物、皮膚外用剤をはじめ、各種の化学物質や、健康食品等を含む趣旨である。

【0055】また、上記システムは、生体として動物を用いた薬品の毒性試験や、安全性薬理試験だけに限らず、動物による安全性試験に入る前の変異原性試験や、薬効薬理試験や一般薬理試験、薬物動体試験、あるいは、薬品を人体に投与する臨床試験等にも応用することができる。また、非GLPの試験に応用することも可能である。これらの場合でも、同様の作用効果を奏する。

【0056】また、上記各実施の形態では、本発明のプログラム選択起動システムを、薬品試験データ試験システムに適用した例を示したが、これに限定するものではなく、例えば、生産管理システム、受注管理システム、顧客管理システム、売上げ管理システム等各種の業務管理システム等に適用することができる。これらの場合でも、同様の作用効果を奏する。

【0057】

【発明の効果】以上のように、本発明のプログラム選択起動システムによれば、データ項目および/または操作ごとに機能分割された複数のプログラムが独立して存在するため、一部のプログラムにバージョンアップ等が合った場合、そのプログラムだけの動作確認を行えばすむようになる。したがって、システム運用開始後の動作確認を確実に行ってGLP等を保証することができるようになる。また、使用する可能性の低い不要なプログラムは導入しなくてもすむため、システムの導入コストや運用コストを大幅に引き下げることもできる。

【図面の簡単な説明】

【図1】本発明のプログラム選択起動システムの一実施の形態を示すシステム構成図である。

【図2】プログラム起動手段による表示画面の一例を示す図である。

【図3】上記プログラム選択起動システムの動作を説明するフローチャート図である。

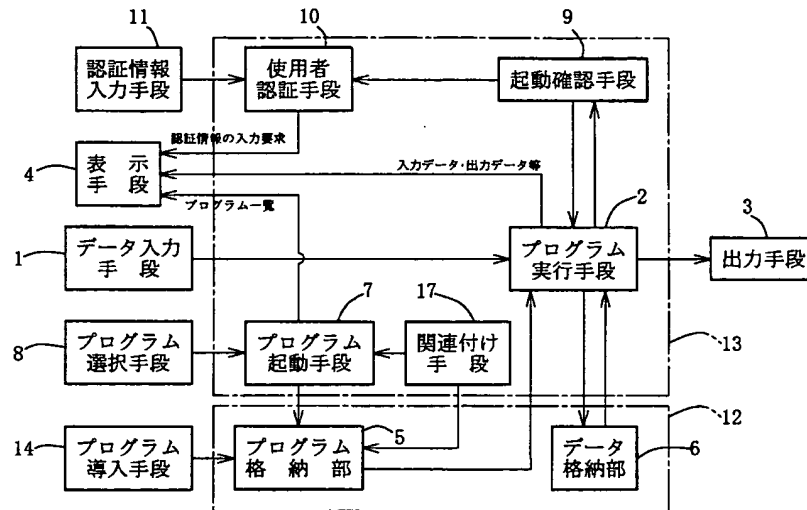
【図4】本発明の第2の実施の形態のプログラム選択起動システムを示すシステム構成図である。

【図5】上記プログラム選択起動システムの動作を説明するフローチャート図である。

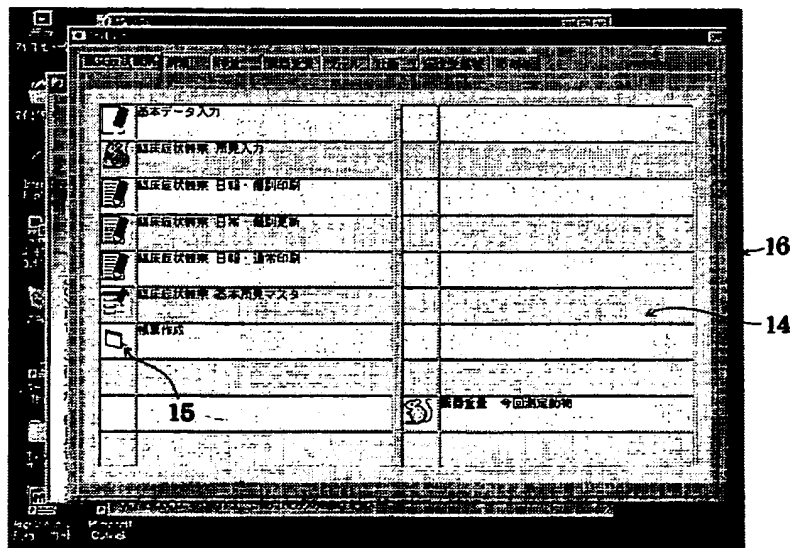
【符号の説明】

- 4 表示手段
- 5 プログラム格納部
- 7 プログラム起動手段
- 8 プログラム選択手段

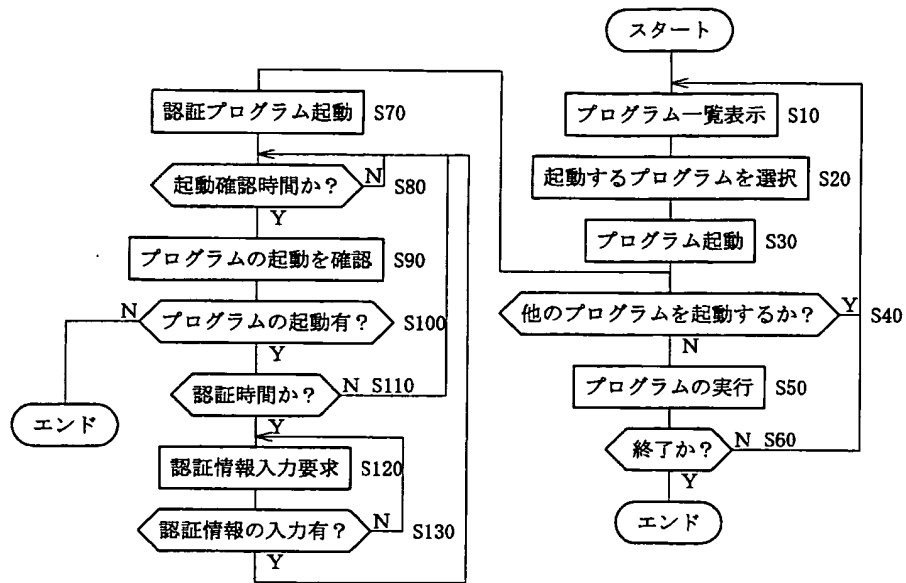
【図1】



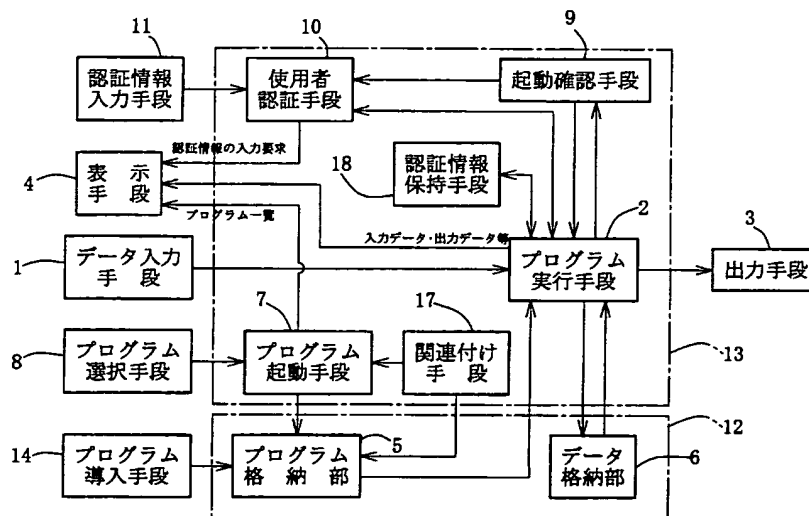
【図2】



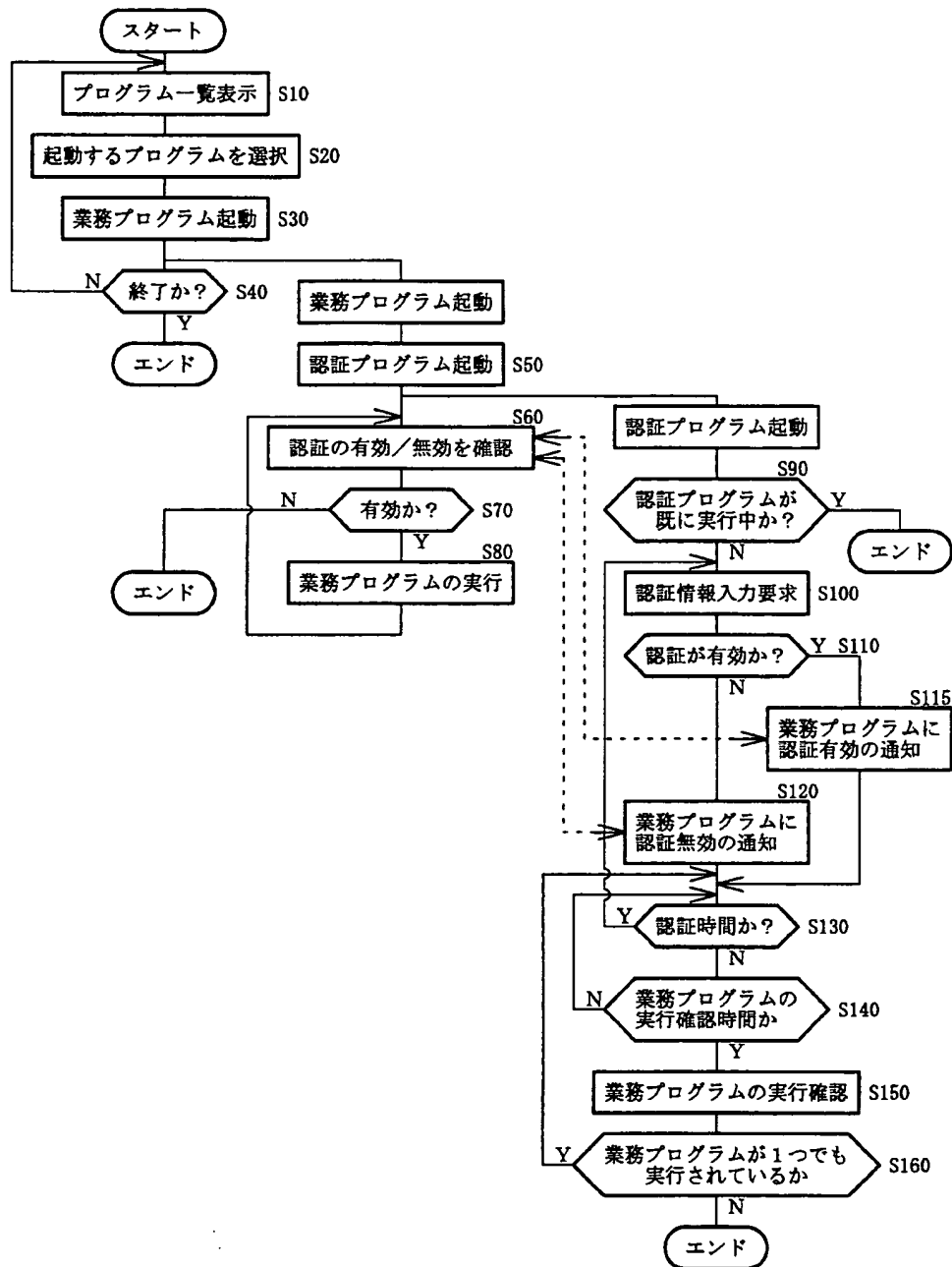
【図3】



【図4】



【図5】



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